No. 23-10362

In the United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D., *Plaintiffs-Appellees*,

v.

U.S. FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, COMMISSIONER OF FOOD AND DRUGS; JANET WOODCOCK, M.D., IN HER OFFICIAL CAPACITY AS PRINCIPAL DEPUTY COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; PATRIZIA CAVAZZONI, M.D., IN HER OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants-Appellants*,

v.

DANCO LABORATORIES, L.L.C, *Intervenor – Appellant*.

Appeal from the United States District Court for the Northern District of Texas, Amarillo Division, Case No. 2:22-CV-223-Z
The Honorable Matthew J. Kaczmaryk, Judge Presiding

AMICI CURIAE BRIEF OF ADVANCING AMERICAN FREEDOM, 40 DAYS FOR LIFE, AFA ACTION, AMERICAN CORNERSTONE INSTITUTE, AMERICAN FAMILY ASSOCIATION, AMERICAN VALUES, ANGLICANS FOR LIFE, CATHOLIC VOTE EDUCATION FUND (CVEF), CENTER FOR POLITICAL RENEWAL, CHARLIE GEROW, CHRISTIAN LAW ASSOCIATION, COMMITTEE FOR JUSTICE, CONGRESSWOMAN VICKY HARTZLER, CORNWALL ALLIANCE FOR THE STEWARDSHIP OF CREATION, DR. JAMES DOBSON FAMILY INSTITUTE, EAGLE FORUM, FOCUS ON THE FAMILY, FRONTLINE POLICY COUNCIL, INTERNATIONAL CONFERENCE OF EVANGELICAL CHAPLAIN ENDORSERS, MINNESOTA FAMILY COUNCIL, MISSOURI CENTER-RIGHT COALITION, MONTANA FAMILY FOUNDATION, MY FAITH VOTES, NATIONAL CENTER FOR PUBLIC POLICY RESEARCH, NATIONAL RELIGIOUS BROADCASTERS, PROJECT 21, THE FAMILY FOUNDATION (VIRGINIA), AND YOUNG AMERICA'S FOUNDATION IN SUPPORT OF APPELLEES

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INTEREST OF AMICI CURIAE

Movant, Advancing American Freedom (AAF) promotes and defends policies that elevate traditional American values, including the rights to life, liberty, and the pursuit of happiness. Advancing American Freedom, joined by twenty-nine other pro-life groups, sent a Freedom of Information Act (FOIA) request to FDA because the women whose health and safety were jeopardized by this drug deserve answers and accountability about the approval process for the chemical abortion drug.[1] AAF believes this case permits this Court to clearly articulate that the FDA does not merit judicial deference under *Chevron v. NRDC*, 467 U.S. 837 (1984) nor under *Auer v. Robbins*, 519 U.S. 452 (1997).[2]

The American Cornerstone Institute is a nonpartisan, not-for-profit organization founded by pediatric neurosurgeon and 17th Secretary of the Department of Housing and Urban Development Dr. Benjamin S. Carson. The Institute's mission is to educate the public on the importance of Faith, Liberty, Community, and Life. The preservation of life, from conception onwards, is a central tenet of the American Cornerstone Institute.

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[1] Freedom of Information Act Request: Mifepristone (April 27, 2023), https://advancingamericanfreedom.com/wp-content/uploads/2023/04/AAF-FOIA-Request-to-FDA-Re-Mifepristone-4-27-23.pdf

[2] All parties received timely notice and have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part. No person other than *Amicus Curiae* and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

The mission of the American Family Association is to inform, equip, and activate individuals and families to transform American culture and to give aid to the church, here and abroad, in its calling to fulfill the Great Commission. AFA Action is the governmental affairs affiliate of American Family Association and is dedicated to advancing Biblical and Family values by influencing public policy.

American Values (AV) is a non-profit organization committed to uniting the American people around the vision of our Founding Fathers. AV is deeply committed to advancing a culture of life in public policy and to defending the sanctity of life in the law. This case is important to AV because it offers this Court a chance to correct a grave error; FDA does not merit *Chevron* nor *Auer* deference.

Anglicans For Life (AFL) is a nonprofit organization that promotes and defends traditional American values, including the uniquely American idea that all men are created equal and endowed by their Creator with unalienable rights to life, liberty, and the pursuit of happiness. This case is important to AFL because it presents an opportunity for this Court to demonstrate that the FDA does not merit judicial deference under *Chevron* nor under *Auer.*

CatholicVote.org Education Fund ("CVEF") is a nonpartisan voter education program devoted to promoting an authentic understanding of ordered liberty and the common good. Members of CVEF are committed to building a culture that respects the sanctity of life and believe that the people, acting through their elected

representatives, have a moral obligation to protect the life and health of the mother and child. CVEF joins as an *amicus* because it believes that in this case public officials have abused their authority.

The purpose of the Center for Political Renewal (CPR) is to provide policy guidance, model legislation and related resources to lawmakers and allied organizations seeking to advocate for policies that further Christian culture.

For over 50 years, Christian Law Association, a pro-life ministry committed to human flourishing, has provided free legal assistance to Bible-believing churches and Christians who are experiencing difficulty in practicing their religious faith because of governmental regulation, intrusion, or prohibition in one form or another. The outcome of this case is significant to us because we believe in the sanctity and preservation of human life from conception onwards, and are thus concerned that women are at significant risk because the FDA did not follow appropriate protocols in approving this drug

Founded in 2002, the Committee for Justice (CFJ) is a nonprofit, nonpartisan legal and policy organization dedicated to preserving both the Constitution's limits on governmental power and its separation of powers. Central to that mission is ensuring that administrative agencies like the FDA interpret rather than rewrite federal statutes and that the federal courts push back against, rather than defer to, agencies when they exceed their proper role. CFJ files amicus curiae briefs in key

cases, supports constitutionalist nominees to the federal judiciary, and educates the American public and policymakers.

The Cornwall Alliance is a network of evangelical Christian scholars dedicated to educating the public and policymakers about Biblical earth stewardship, economic development for the poor, and the gospel of forgiveness of sins and reconciliation with God by grace through faith in the atoning death and vindicating resurrection of Jesus Christ.

The Dr. James Dobson Family Institute is a nonprofit organization that uplifts and defends the biblical and traditional framework of the family, which includes parental rights and the freedom to exercise one's religious beliefs. These most foundational rights have been preserved for centuries and must be maintained for the institution of the family to remain intact and flourish.

Eagle Forum is a nonprofit organization with the mission to enable conservative and pro-family men and women to participate in the process of self-government and public policymaking so that America will continue to be a land of individual liberty, with respect for the nuclear family, public and private virtue, and private enterprise. Eagle Forum has long advocated for policies that appreciate and strengthen the unique role of women in society, including their health, education and welfare, while promoting respect for the differences between the sexes and supporting the rights of all Americans.

"Focus on the Family is a Christian not-profit ministry, headquartered in Colorado, committed to strengthening the family in the United States and abroad by providing help and resources that are grounded in biblical principles. Focus on the Family educates and advocates for parental rights and protecting the innocence and lives of children, including orphans and pre-born babies. The president of Focus on the Family, Jim Daly, hosts the flagship Focus on the Family radio broadcast about family issues carried daily on 2,000 radio outlets in the United States and heard weekly by nearly 7 million listeners."

40 Days for Life is an internationally coordinated 40-day campaign that aims to end abortion locally through prayer and fasting, community outreach, and a peaceful all-day vigil in front of abortion businesses. The first 40 Days for Life campaign took place in 2007, since then reaching over 1,000 cities in 63 countries.

Frontline Policy Council is a nonprofit organization that advocates for policies for the good of our neighbor.

The International Conference of Evangelical Chaplain Endorsers (ICECE) is a conference of evangelical organizations that endorse Christian clergy to be chaplains in the military and other limited-access organizations. ICECE supports challenges to agencies' unlawful expansions of their power, especially in the absence of clear congressional or constitutional authority in areas where political agendas are more important than science and medical safety.

Minnesota Family Council's mission is to strategically advance biblical truth in the public arena for life, family and religious freedom, through citizenship worthy of the gospel of Christ.

My Faith Votes is a non-partisan movement that motivates, equips, and activates Christians in America to vote in every election, transforming our communities and influencing our nation with biblical truth.

The National Center for Public Policy Research is a communications and research foundation dedicated to providing free market solutions to today's public policy problems. We believe that the principles of a free market, individual liberty and personal responsibility provide the greatest hope for meeting the challenges facing America in the 21st century. We join this *amicus* brief to endorse the principle that a single set of objective rules must be applied consistently and neutrally.

National Religious Broadcasters (NRB) is a non-profit, membership association that represents the interests of Christian broadcasters throughout the nation. Most of its approximately 1100 member organizations comprise radio stations and networks, television stations and networks, and the executives, principals, and production and creative staff of those broadcast entities. Since 1944, the mission of NRB has been to help protect and defend the rights of Christian media and to maintain access for Christian communicators. Additionally, NRB seeks to

effectively minister to the spiritual welfare of the United States of America through the speech it advances to the public.

Project 21, a national leadership network for black conservatives, promotes the views of black citizens whose entrepreneurial spirit, dedication to family, and commitment to individual responsibility have not traditionally been echoed by the nation's civil rights establishment. Project 21 has participated as *amicus curiae* in significant cases involving equal protection principles. *See*, e.g., *Shelby Cty. v. Holder*, 570 U.S. 529 (2013); and *Bartlett v. Strickland*, 556 U.S. 1 (2009).

The Family Foundation (TFF) is a Virginia non-partisan, non-profit organization committed to promoting strong family values and defending the sanctity of human life in Virginia through its citizen advocacy and education. TFF serves as the largest pro-family advocacy organization in Virginia. Its interest in this case is derived directly from its concern to advance a culture in which children are valued, religious liberty thrives, and marriage and families flourish.

The mission of Young America's Foundation (YAF) is to educate and inspire young Americans from middle school through college with the ideas of individual freedom, a strong national defense, free enterprise, and traditional values. This case is important to YAF because it presents the Court an opportunity to curb unconstitutional government overreach and strengthen fundamental principal of separation of powers, without which the American experiment would not exist.

SUMMARY OF THE ARGUMENT

In October 2006, a yearlong Congressional investigation culminated in a report outlining the significant scientific and legal shortcomings of the FDA's approval in 2000 of the drug mifepristone for use as a chemical abortifacient. The FDA approved mifepristone under Subpart H, designed to allow the agency to approve drugs that would provide meaningful therapeutic benefits over existing treatments for serious and life-threatening illnesses such as AIDS. Because abortion is not a treatment, and pregnancy is not an illness and is not, itself, serious or life-threatening, and because mifepristone is more dangerous and less effective than the alternative, surgical abortion, the FDA abused its own regulation in approving mifepristone in 2000.

When reviewing this agency action, this Court should not defer to FDA's interpretations; rather, this Court should exercise independent judgment as to the legality of FDA's actions. Judicial deference permits Federal agencies like FDA to expand their power, undermining the separation of powers and the freedoms that constitutional principle exists to protect. The power to legislate belongs to Congress alone and the power to interpret belongs to the courts. Agencies, part of the executive branch, may only apply existing law. Agency power does not include changing the plain meaning of those regulations outside a notice-and-comment regulatory process.

Chemical abortions were and are a more dangerous and less effective form than surgical abortion. Unlawful expansion of chemical abortion undermines States' efforts to protect their legitimate interests. The FDA's increasingly lax reporting and use requirements for the drugs make it almost impossible to determine the true scope of the danger posed by chemical abortion drugs. For all these reasons, this Court should uphold the district court's order staying the FDA's unlawful approval of mifepristone as an abortifacient in both its name-brand and generic forms and to grant all of the Plaintif-Appellees' other prayers for relief.

ARGUMENT

Quis custodiet ipsos custodes? (Juvenal, *Satire VI*, lines 347–348). For some 2000 years, the problem of "who guards the guardians" has challenged good governance. What happens when the FDA, entrusted with basing decisions on sound science, trucks in junk science and maneuver to achieve a desired political outcome? In 2006, the United States House of Representatives Government Reform Committee's Subcommittee on Criminal Justice, Drug Policy, and Human Resources culminated a year-long investigation with a hearing on mifepristone entitled *RU-486: Demonstrating a Low Standard for Women's Health?* [3]

[3] *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006), available at https://archive.org/details/gov.gpo.fdsys.CHRG-109hhrg31397. Video available at https://www.c-span.org/video/?192580-1/ru-486-health-safety-standards#.

("Congressional Hearing") at which Janet Woodcock, M.D., defendant in the lower court, served as a witness on behalf of FDA. A witness to the danger of this drug was Monty Patterson, father of Holly Patterson, who was killed by mifepristone just after her eighteenth birthday.[4] Congressional Hearing at 117-121. Subcommittee staff issued a subsequent report entitled *The FDA and RU-486: Lowering the Standard for Women's Health*[5] ("Congressional Report"). This report summarized the Congressional investigation into the scandalous flaws in the FDA's September

[4] "I said I wanted to show you a picture of my daughter so at least you see what I have lost and actually what she lost. I owe and dedicate my presence here to those who have no voice and particularly to my daughter, Holly, who died at 18, and the other women who have died or have been seriously hurt by taking the RU-486 medical abortion drug regimen as a solution to their unplanned pregnancy. I am here to testify about my personal experience as the father of a victim of this drug and my consequent knowledge, experiences, and views pertaining to RU-486, the drug... Twelve days after Holly's 18th birthday, on September 10, 2003, she walked into a Planned Parenthood clinic to be administered an RU-486 medical abortion regimen. By the 4thday, she was admitted to the emergency room of a local hospital. She was examined. She was given pain killers. She complained of bleeding, cramping, constipation, and pain, but subsequently, she was sent home. Seven days after taking RU-486, Holly returned to the same emergency room hospital complaining of weakness, vomiting, abdominal pain. Hours later, I was called to the hospital, where I found her surrounded by doctors and nurses, barely conscious and struggling to breathe. Holly was so weak she could barely hold onto my hand. Feeling utter disbelief and desperation, I watched Holly succumb to a massive bacterial infection as a result of a drug-induced abortion with RU-486." Congressional Hearing at 120.

[5] *The FDA and RU-486: Lowering the Standard for Women's Health*, House of Representatives Government Reform Committee; Subcommittee on Criminal Justice, Drug Policy, and Human Resources (Oct. 2006), available at https://www.liveaction.org/news/wp-content/uploads/2020/08/SouderStaffReportonRU-486.pdf.

28, 2006 approval of RU-486 ("mifepristone") as a chemical abortifacient[6], clearly a political rather than scientific decision. Following years of political pressure from Congressional Democratic chairmen Ron Wyden, Ted Weiss, and Henry Waxman in the early 1990s (Lader 1991 at 114), the Congressional Report made publicly known the deep Clinton White House political involvement beginning on President Clinton's inaugural day in pushing FDA to find a way to get mifepristone introduced into America even before a new drug application was received. Congressional Hearing at 3-66. The Congressional Report details the uncontroverted safety concerns that exceeded alternatives at the time of FDA's abusive approval of mifepristone as an abortifacient under the Subpart H approval process.

As Staff Director and Senior Counsel of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources from 2003-2007, I supervised the investigatory team led by staff attorney Michelle Powers Gress identifying the FDA problems detailed in Congressional Report. I write today on behalf of Advancing American Freedom and *amici* because the problems apparent at the time of the 2006 Congressional Report remain today, even as the FDA continues to decrease the

[6] Hannah Levintova, "The Abortion Pill's Secret Money Men: The untold story of the private equity investors behind Mifeprex—and their escalating legal battle to cash in post-Dobbs," *Mother Jones*, (March/April 2023), available at https://www.motherjones.com/politics/2023/01/abortion-pill-mifepristone-mifeprex-roe-dobbs-private-equity/ .

protective protocols and the collection of adverse event reports associated with chemical abortions.

Finally, after years of stonewalling Congress and complainants, the FDA is being called to account just as another Administration seeks to bend FDA to abandon all reasonable protections, even in States that exercise their inherent authority to safeguard the safety of both mothers and their preborn children by restricting use of chemical or surgical abortion.[7] The district court's stay of the FDA's approval of the mifepristone as an abortifacient must be upheld because of the clear legal deficiencies of mifepristone's approval process is not entitled to deference.

The FDA's decades-long avoidance of public review must end. Just as mifepristone partisans tried to withhold FDA documents over months from Congress and just as Danco declined to testify under oath (Congressional Hearing, 68), FDA senior bureaucrats have manipulated the agency to extend a 180-day review to nearly two decades, a Dickensian *Bleak House*-testing of the outer limits of *Chevron* and *Auer*. Clearly, the "FDA [has] stonewalled judicial review," *Alliance for Hippocratic Medicine v. FDA*, ---F. Supp. 3d ----, 2023 WL 2325871, 1 (N.D. Tex. 2023) because FDA knows that approving mifepristone for abortifacient use violated

[7] The States' legitimate interest in protecting the life of the unborn and the safety and health of the mother are recognized by the Court today and were recognized at the time of the FDA's approval. *See Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022); *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 846 (1992).

its own rules in 2000. If the FDA were confident in its 2000 determination, especially in a past legal environment so obsequious to FDA decisions under *Chevron v. NRDC*, 467 U.S. 837 (1984) and *Auer v. Robbins*, 519 U.S. 452 (1997), it would have allowed judicial review to proceed long ago. Too many victims, named and unnamed, have been harmed or destroyed by this illegally approved chemical abortion drug. This Court should uphold the stay issued by the district court.

I. The FDA Approved Mifepristone Without Regard for the Significant Safety Concerns Apparent at the Time of Approval.

As will be discussed in greater detail below, the FDA regulation under which it approved the mifepristone as an abortifacient requires that new drugs approved through that process provide a "meaningful therapeutic benefit over existing treatments." 21 CFR § 314.500. There was ample evidence prior to the FDA's approval of mifepristone in 2000 that chemical abortions provided no such benefit over the existing procedure, surgical abortions.

In 1981, human trials of mifepristone took place in Geneva, Switzerland after seventeen months of animal research. Congressional Report at 10. Even those initial human trials indicated the dangers of mifepristone when used as an abortifacient. Those trials resulted in two unsuccessful abortions out of eleven attempts, with two of the eleven women requiring further medical intervention including, in one case, emergency surgery and a blood transfusion. Congressional Report at 10. The next round of trials, conducted in several different countries, produced widely varied

success rates from as low as fifty-four percent (54%) to as high as ninety percent (90%). Congressional Report at 10-11. That success rate increased to ninety-four percent (94%) in one trial when doctors in Sweden began to administer mifepristone, though it remained significantly lower than the ninety-nine percent (99%) success rate of surgical abortion at the time.[8] *Id*.

After mifepristone was approved in France, a committee of experts reviewed data on 30,000 women who had used mifepristone as an abortifacient and found numerous significant risks associated with use of the drug. Congressional Report at 11-12. Further, the World Health Organization released a study in 1991 in which just under three percent (3%) of women with completed abortions and almost thirty percent (30%) of those with incomplete abortions "had to be given 'antibiotic therapy to prevent or cure suspected genitourinary infection' during the six-week follow-up period." Congressional Report at 12, n. 63.

Writing before mifepristone's approval, the FDA's medical reviewer, found that chemical abortions were of limited value given the short time period during which they were available, the need for three visits to a medical facility during the process, the need for a follow-up visit to ensure that surgical intervention is not required, and because of specific problems with chemical abortion in comparison to

[8] Success was defined as fetal death without the need for further medical intervention.

surgical abortion. Congressional Report at 29-30. In particular, the reviewer noted the higher failure rates of chemical abortion, the greater frequency of symptoms including cramping, nausea, and vomiting, and the increased blood loss associated with chemical as opposed to surgical abortions. Congressional Report at 29-30.

Further, the FDA Medical Officer's review found that for women with pregnancies up to seven weeks, the original gestational limit approved by the FDA, the failure rate was almost eight percent (8%), with the percentage increasing at longer gestational periods, up to twenty-three percent (23%) for pregnancies at 57-63 days. Congressional Report at 31.

Because these failure rates were higher and the symptoms associated more frequent, and because chemical abortion provided no other significant benefits over the alternative, surgical abortion, improved efficacy, and safety could not have justified the FDA's approval of mifepristone for abortifacient use under its own regulation.

II. The FDA's Approval of Mifepristone for Use as an Abortifacient is Not Entitled to *Auer* Deference Because It Violated the Plain Language of Subpart H of CFR Part 314.

Federal executive agencies derive whatever power they may have from Congress by legislation empowering them to exercise legal control over a particular policy domain. When an agency's interpretation of that legislation is challenged in court, courts will often accept the agency's interpretation if the language of the

statute is ambiguous, and if the agency's interpretation of that statute is reasonable. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

In *Auer v. Robbins*, 519 U.S. 452 (1997), the Supreme Court established a similar doctrine that applies to an agency's interpretation of its own regulations. When an agency interprets one of its own regulations, and that regulation is genuinely ambiguous (however that may have come about), the agency's interpretation may be entitled to deference. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019). This judicial approach, called *Auer* deference, has not been overturned, but its future is uncertain. *Id*. at 2425 (Gorsuch, J. concurring) (Justice Gorsuch, joined by Justices Thomas, Alito, and Kavanaugh in relevant parts, arguing that it is time to overrule *Auer)*. Regardless, as explained below, it does not apply here because the language of Subpart H is clear and was flagrantly violated by the FDA's approval of mifepristone as an abortifacient.

Subpart H, an FDA regulation promulgated to address the AIDS crisis, entitled *Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses*, allows the FDA to approve new drugs to treat "serious or life-threatening illnesses" and "that provide meaningful therapeutic benefit to patients over existing treatments." 21 CFR § 314.500. Further, the FDA may approve the new drug only "on the basis of adequate and well-controlled clinical trials." 21 CFR § 314.510.

Thus, its purpose is to allow for expedited approval of new drugs when doing so would allow for improved treatments of patients whose illnesses are serious and who need better treatment options. The FDA, in approving the mifepristone regimen for chemical abortions, acted outside of this clear purpose and violated the plain requirements of the regulation's text.

Auer deference only applies "to an agency's reasonable interpretation of its own regulations when the regulation's text is 'genuinely ambiguous,' and the 'character and context of the agency's interpretation entitles it to controlling weight.'" *Johnson v. BOKF Nat'l Ass'n*, 15 F.4th 356, 362 (5th Cir. 2021) (quoting *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414, 2416 (2019)). Genuine ambiguity is a requirement the Court takes seriously. "When we use that term, we mean it—genuinely ambiguous, even after a court has resorted to all the standard tools of interpretation." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019). In this case, the language of Subpart H is unambiguous, and the FDA's interpretation of that language is just as clearly contrary to that language in several ways.

A. Pregnancy is not a serious or life-threatening illness, and thus is not the type of condition Subpart H is intended to address, and so Auer *deference should not apply.*

Subpart H exists to allow for the approval of new drugs for the treatment of "serious or life-threatening illnesses." 21 CFR § 314.500. Most importantly, pregnancy is not an illness. As noted by the Subcommittee report, the FDA's letter

to the Population Council,[9] mifepristone's sponsor for FDA approval in the United States, referred to "the termination of an unwanted pregnancy" as the "serious condition" to be addressed by the approval of mifepristone. (Congressional Report 19, n. 99). However, the language of the regulation does not provide for approval of drugs for serious conditions but rather for illnesses. Although pregnancy may occasionally result in serious or life-threatening conditions, pregnancy itself is neither serious nor life-threatening. Because *Auer* deference only applies to ambiguous regulatory language, it is inapplicable here because the plain meaning of Subpart H is as clear as is the FDA's rank violation of the requirements of Subpart H.

B. Chemical abortions did not provide a "meaningful therapeutic benefit over existing treatments" because chemical abortion was neither safer nor more effective than surgical abortions.

Subpart H requires that new drugs approved through its process "provide meaningful therapeutic benefit to patients over existing treatments." 21 CFR § 314.500. The regulation gives examples of such therapeutic benefits as the "ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy." *Id*. Even if abortion may constitute a

[9] "The Population Council is a nonprofit founded in 1952 by John D. Rockefeller III to address supposed world overpopulation." Population Council, https://www.influencewatch.org/non-profit/population-council/ (last visited Feb. 9, 2023).

treatment with therapeutic benefits, it was clear from the evidence at the time of approval in 2000 that chemical abortion was both more dangerous for the woman and less effective than surgical abortion.

The report quotes the FDA's Approval Memo to the Population Council as describing the supposed therapeutic benefit of chemical over surgical abortions as being the "avoidance of a surgical procedure." Congressional Report at 21, n. 106 (internal quotation marks omitted). The Congressional Report identifies four problems with this idea.

First, the report notes that mifepristone was not approved only for use for women intolerant of surgical abortions, as would be expected for a less safe, less effective form of abortion. Congressional Report at 22. The report says, "[the] FDA baldly asserted that there was a clinical benefit for chemical abortion and made no effort to produce statistical evidence of an actual benefit." Congressional Report at 22.

Second, the report points to the fact that a substantial portion of women using mifepristone to induce an abortion ultimately required surgical intervention thus casting doubt on the supposed benefit of chemical abortions because "women must be able to tolerate the surgical procedure" if they are going to attempt a chemical abortion. Congressional Report at 22. As the report notes, the FDA must show that

there is, in fact, some clinical benefit to an approved drug, which they did not do in this case. *Id*.

Third, the report notes that the fact that some patients may prefer one form of treatment over another is not itself a clinical benefit.

Finally, the report notes that the FDA medical officer, prior to approval of mifepristone, made comments to the effect that bleeding was a significantly more prevalent and serious issue in multiple studies comparing chemical to surgical abortions. "Given these comments," the report summarizes, "it is impossible to conclude that [mifepristone] medical abortions provide a meaningful therapeutic benefit over surgical abortion." Congressional Report at 23.

C. Approval of Mifepristone as an abortifacient was not based on "adequate and well-controlled studies."

Subpart H also requires that the FDA's approval of a drug be "on the basis of well-controlled clinical trials." Further, 21 CFR 314.126(e) says, "Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness." In this case, the data relied on by the FDA was not concurrently controlled. *See* Congressional Report at 15-19. As the Congressional Report notes, the trials the FDA relied on were not concurrently controlled against first trimester surgical abortion. Congressional Report at 14. As part of the investigation for the report, the subcommittee held a hearing in which the FDA Deputy Commissioner for Operations, Dr. Janet Woodcock (defendant in the

case below), said that a historical control was used in assessing the trials of mifepristone. Congressional Hearing at 92. In other words, the trials were controlled against the existing data on pregnancy, miscarriage, and abortion.

The Congressional Report points out three problems with the FDA's assertion of non-concurrent control as a basis for the approval of mifepristone. First, the "FDA's assertion that the French and U.S. trials were historically controlled appears to be a *post hoc* assertion." Congressional Report at 17. The study that reported on the American trials did not mention a control group and a statement from an FDA statistician who reviewed French trials suggested a lack of concurrent control groups in those trials as well. Congressional Report at 17.

Second, the American studies of mifepristone excluded women with numerous medical issues, but the FDA acknowledged that the historical data, the control group, was data from the general population and thus did not exclude women with those health problems. Congressional Report at 18. As a result, the apparent safety of mifepristone relative to surgical abortion was likely inflated because the data on chemical abortions was gathered from relatively healthy women, while the data on surgical abortions included women with health problems who would have been excluded from the studies of chemical abortion. Regardless, because the trial and control groups were not matched in terms of their health background, they are not a "meaningful control." Congressional Report at 18. As the report concludes, "If it

was not possible to match the populations with the historical data set, then a concurrent control should have been used." *Id.*

Finally, the report notes that using historical data rather than a concurrent control group results in "defining the clinical endpoint too restrictively." Congressional Report at 18. In other words, surgical abortions and miscarriage are not binary, they do not "produce only simple zero or one outcomes." *Id.* As the report notes, "A control should have been used in the [mifepristone] trial that compared different methods of producing the experimental outcome – first-trimester pregnancy termination – while assessing each method's ability to manage highly predictable, regular complications of medical abortion (i.e., hemorrhage, incomplete abortion)." *Id.*

In sum, the FDA only claimed that its studies were controlled after approval, the American cherry-picked studies of mifepristone excluded women with numerous medical issues potentially inflating the appearance of safety of chemical as opposed to surgical abortion, and the historical data used as a non-concurrent control provided, at best, a low-resolution picture of the safety and effectiveness of chemical as opposed to surgical abortions. Thus, because the FDA violated the clear language of Subpart H, it is not entitled to *Auer* deference and the district court's stay of the FDA's approval of mifepristone for abortifacient use should be upheld.

III. Chemical abortion continues to pose a significant safety risk for women, made worse by the lax reporting requirements approved by the FDA.

As discussed above, the FDA knew about the significant, negative health consequences of mifepristone before approving it for abortifacient use in the United States. Despite the continued danger of chemical abortion since its approval, the FDA has weakened the reporting requirements, casting doubt on its claims about the safety of mifepristone.

A. The danger to women posed by chemical abortions has not abated in the 23 years since its approval by the FDA.

By 2006, the dangers of chemical abortion had become even more evident than they were when the FDA approved the drugs for that use in 2000. In her testimony in the Congressional Hearing in May of 2006, Dr. Donna Harrison (a Plaintiff in the lower court) said,

> In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion.

Congressional Hearing at 142. Dr. Harrison added that no risk factors predicted such hemorrhage, and that it was life threatening for women without access to immediate medical care. *Id*. Such dangers have been ignored by the FDA in its effort to push mifepristone over the past 23 years.

Knowledge that has become available since the Congressional Report was published in 2006 is no more encouraging. Several studies have shown the medical risk associated with the use of chemical abortion. Ten percent (10%) of women, after use of chemical abortion, require follow-up medical treatment for failed or incomplete abortion, Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BJM, April 20, 2011, at 4, and twenty percent (20%) of women who use mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections. Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009). This rate of adverse events is four times greater than the adverse event rate of surgical abortion. *Id*. Furthermore, five percent (5%) of women who undergo a chemical abortion will need to be rushed to an emergency room within thirty days; a rate fifty percent (50%) higher than those who undergo surgical abortions. James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions*, 1999-2015, Health Serv. Rsch. & Managerial Epidemiology, Nov. 9, 2021.

FDA's inexplicable cutback on adverse event reporting requires researchers to look overseas for data on mifepristone's harm to women. Even recent experience with mifepristone bears out the fact that it continues to be more dangerous than

surgical abortion, obviating FDA's Subpart H approval. "During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction [chemical abortion] at home and then full telemedicine."[10] Miller at 288, 296. British researchers, "using our rights under the Freedom of Information Act… asked each of the ten NHS Ambulance Trusts in England to provide data related to the number of emergency ambulance responses made when the caller indicated complications arising from the use of abortion pills, a combination treatment of mifepristone and misoprostol. Data was requested for three time periods: A – during 2018, when all medical abortions were provided in a clinic; B – during 2019, when women were able to self-administer misoprostol (the second part of the combined treatment) at home, after having received the mifepristone (the first part of the combined treatment) at an abortion clinic; C – from

[10] Even the most zealous advocates for mifepristone did not countenance that: "Prescribing RU 486 will maintain the same doctor-patient relationship that accompanies the use of an antibiotic or any drug." Lader 1995 at 17.

April 2020, when women were able to self-administer both mifepristone and misoprostol at home… Data obtained from five NHS Ambulance Trusts in England, show that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic." Duffy at 1. "In a related freedom of information investigation, we found that complications arising from the failure of medical abortion treatment result in 590 women presenting at the emergency department of their local NHS hospital in England every month. The treatment failure rate is 5.9%, 1-in-17." *Id.*

B. The FDA's slackened reporting standards put women at further risk and smack of politics rather than healthcare.

In 2023, adverse events are widely underreported because the FDA only requires prescribers to report deaths, not other less-than-lethal adverse events associated with mifepristone. In 2000, the FDA approved mifepristone with certain safeguards and requirements to decrease the dangers mifepristone could pose to women, consistent with Subpart H. *See* 21 C.F.R. § 314.520. Although compliance with those requirements was insufficient to prevent adverse events, they were much more stringent than the requirements imposed today. Among those requirements in 2000, prescribers were obligated to report non-fatal but serious adverse events to the drug manufacturer. Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000),

https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm. Shockingly, beginning in 2016, prescribers need only report deaths associated with the drug, not other serious adverse events. Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download. Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download. Imposing ignorance of adverse event reporting requirements and then claiming the drug is safe because there are so few reports of adverse events is a Through-The-Looking-Glass approach to public health that intentionally obscures the true dangers of mifepristone.

The data relied upon by the FDA when it approved mifepristone as an abortifacient in 2000 was insufficient to support its finding that chemical abortion was a safe alternative to surgical abortion. In the ensuing two decades, even the paucity of information collected by the FDA on the safety of chemical abortion continues to show significant dangers for women using mifepristone. Despite evidence of significant danger, the FDA continues to slacken safeguards for use of mifepristone and for reporting the dangerous consequences its use. Such reckless disregard of data collection on women's well-being smacks more of political maneuver than medical science.

CONCLUSION

For the forgoing reasons, we urge the Court to uphold the district court's order staying the FDA's unlawful approval of the mifepristone as an abortifacient in both its name-brand and generic forms and to grant all of the Plaintiffs-Appellees' other prayers for relief.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,355 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Times New Roman 14-point font in text and Times New Roman 14-point font in footnotes produced by Microsoft Word software.

/s/ J. Marc Wheat
J. Marc Wheat

CERTIFICATE OF SERVICE

I hereby certify that on May 12, 2023, an electronic copy of the foregoing brief was filed with the Clerk of this Court using the CM/ECF system, which will serve all counsel of record.

/s/ J. Marc Wheat
J. Marc Wheat